EXHIBIT P

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ORIGINAL ARTICLE

Long-term follow-up of the retropubic tension-free vaginal tape procedure

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Abstract
Introduction and hypothesis Retropubic tension-free vaginal tape (TVT) was introduced in 1996 as a new and innovative surgical approach in the treatment of stress urinary incontinence (SUI). In this study we evaluate the long-term objective and subjective outcomes in a non-selected patient population 10 years after the retropubic TVT procedure.
Methods All women (603) operated on with retropubic TVT at four gynecological departments from September 1998 through December 2000 were identified, and those still alive (542) were invited to participate in this population-based prospective study. For subjective data a short-form urinary incontinence disease-specific questionnaire was used. For objective evaluation the women underwent a stress test. Data collected were merged with previously stored data in the Norwegian National Incontinence Registry Database.
Results We included 483 women; 327 attended a clinical follow-up consultation and 156 had a telephone interview. Median duration of follow-up was 129 months. Objective cure rate was 89.9 %, subjective cure rate was 76.1 %, and 82.6 % of the patients stated they were "very satisfied" with their surgery (treatment satisfaction rate). Only 2.3 % of the women had undergone repeat SUI surgery. Subjective voiding difficulties were reported by 22.8 %, the majority describing slow stream or intermittency. De novo urgency incontinence increased significantly from 4.1 % 6–12 months after surgery to 14.9 % at the 10-year follow-up.
Conclusions Long-term objective and subjective outcome after retropubic TVT is excellent with a low number of re-operations even in a non-selected cohort of patients.

Keywords Long-term follow-up · Mid-urethral slings · Stress urinary incontinence

Introduction

Retropubic tension-free vaginal tape (TVT) was introduced in 1996 as treatment for female stress urinary incontinence (SUI) [1]. Mid-urethral slings are currently considered the gold standard in the surgical treatment of SUI [2].

A significant rise in the prevalence of urinary incontinence among women was demonstrated in the United States (US) between 2001 and 2008 [3]. The US Food and Drug Administration (FDA) issued in 2011 a notification regarding serious complications associated with the use of transvaginal placement of synthetic meshes in pelvic organ prolapse (POP) surgery and is currently evaluating the use of surgical mesh in the treatment of SUI. As life expectancy increases and more women undergo incontinence procedures using mesh implants, it is of great importance to clarify long-term results and potentially unfavorable outcomes. The short-term results of TVT have been well documented, but few reports have published long-term data [4–8].

There is no consensus at present on how to define long-term follow-up after surgical procedures. A follow-up of

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5 years seems widely used, despite published examples of procedures demonstrating a decline in efficacy with time even after promising early results. As an example, a 14-year follow-up of Burch colposuspension, the previous gold standard in the surgical treatment of SUI, demonstrated a subjective cure rate of only 44 % combined with a high number of women stating voiding difficulties (36 %) [9].

The aim of our study was to evaluate objective and subjective results, re-operation rate for SUI, complications during and following surgery and potential long-term unfavorable outcomes in a non-selected cohort of women 10 years after retropubic TVT.

Materials and methods

This was a population-based prospective study of all women operated on with a retropubic TVT at four gynecological departments within the south-eastern region of Norway from 1 September 1998 to 31 December 2000. All these departments have reported their incontinence surgery data to the Norwegian National Incontinence Registry since its establishment on 1 September 1998 [10]. The majority of gynecological departments in Norway performing incontinence surgery report preoperative subjective and objective data, the type of incontinence procedures and complications, as well as 6–12 months' subjective and objective follow-up data to the National Incontinence Registry.

Tension-free vaginal tape from Gynecare, Ethicon was used, and the procedures were performed as described by Ulmsten et al. [1]. This non-selected patient population consisted of all the women who received TVT as either primary or recurrent surgical treatment for SUI, including those with urethral hypermobility, low urethral closure pressure or mixed urinary incontinence, as well as those undergoing concomitant POP surgery. Written consent for the long-term follow-up was obtained from all participants, the only exclusion criterion was inability to give such consent.

The Regional Committee for Medical and Health Research Ethics in south-eastern Norway deemed the study a quality assurance measure for treatment already established and therefore not in need of ethical approval outside the four departments. Approval was obtained from all department heads and institutional personal data officers.

All the women were invited to attend a 10-year clinical follow-up. Those unable to attend were asked to undergo a structured telephone interview for subjective data. The same short-form urinary incontinence disease-specific questionnaire was used for both categories [11]. The questionnaire has been validated in Norwegian and is used for preoperative, operative, 6- to 12-month routine data as well as for this study with 10-year postoperative data. The following non-validated supplemental questions were added for the 10-year follow-up:

1. How would you characterize the effect of the operation on your current leakage situation? (Choices given: "cured", "better", "unchanged" or "worse")
2. Have you had the feeling that it is difficult to empty your bladder after the operation? If yes, please describe in detail.
3. Has it been persistently painful to empty your bladder after the operation?

A stress test was performed before surgery and at subsequent follow-ups, including at the 10-year clinical follow-up. It consists of pad weighing after 20 jumping jacks on the spot and three forceful coughs in the standing position with 300 ml bladder volume. This stress test has been found to be reproducible [12]. Women unable to perform the test were asked to do a modified version consisting of 10 coughs in the standing position with 300 ml bladder volume. The women were considered objectively cured if the standard or modified stress tests were negative. Any change in pad weight (≥1 g) performing either stress test was considered a positive test and registered as an objective failure. Maximum flow rate (flowmetry) and post-void residual volume (catheter or bladder scanner) were recorded. The vagina was inspected in the semi-lithotomy position for asymptomatic tape exposure.

Primary objective outcomes were cure rate (defined as negative stress test or modified stress test), failure rate (defined as any leakage during the stress tests or the patient having undergone repeat SUI surgery) and re-operation rate (defined as repeat SUI surgery). Primary subjective outcomes were treatment satisfaction rate, cure rate, improved rate, and failure rate. The question on treatment satisfaction has been validated and contains the choices "very satisfied," "moderately satisfied," "neither satisfied nor dissatisfied," "moderately dissatisfied," and "very dissatisfied" [11]. Treatment satisfaction rate was defined as the percentage of women answering they were "very satisfied." Subjective cure rate was defined as the percentage of women answering "cured" on supplemental question 1, improved rate as "cured" or "better," and failure rate as "unchanged" or "worse." Secondary outcome measures were complications during or immediately following surgery recorded in the Registry Database and any long-term unfavorable outcomes discovered at the 10-year follow-up. The women were asked if they remembered any complications. In cases of discrepancy between this information and the patient's data recorded in the Registry Database, the patient's hospital medical records were reviewed. Long-term unfavorable outcomes that were investigated included objective voiding difficulties (maximum flow rate Q_{max}<15 ml/s, post void residuals>100 ml or>200 ml), vaginal mesh exposure, subjective voiding difficulties, recurrent urinary tract infections

(patients stating having received more than three treatments over the last 6 months), de novo urgency incontinence, and persistent painful voiding.

Women having undergone repeat SUI surgery (n=6 for objective data and n=11 for subjective data) were defined as TVT outcome failures when the primary objective outcomes were calculated. These women were excluded when the primary subjective outcomes and long-term unfavorable outcomes were calculated. All outcomes were calculated using per-protocol analysis. Thus, for each outcome variable the denominator was obtained by subtracting women with missing data from the total number of patients.

All participating women had subjective and objective preoperative, operative, and 6- to 12-month data stored in the National Registry Database. After merging the databases, a comparison of objective cure rates and treatment satisfaction rates was performed for the 6- to 12-month and 10-year follow-up data.

The validated questionnaire stratifies into stress- and mixed incontinence [11]. The stress incontinence index ranges from 0 to 12 and the urgency incontinence index from 0 to 8 [11]. In this study we defined de novo urgency incontinence as a woman with no preoperative symptoms of urgency incontinence (urgency incontinence index score=0) who developed postoperative urgency incontinence (urgency index score>0 combined with the need for pad use).

To evaluate whether women operated on in the study departments were representative of the national patient group, we compared the study group with the remaining women in the National Registry Database who had undergone a TVT operation in the same time period (n=747). The preoperative variables age, 24-hour pad test, stress test, post-void residual volume, maximum flow rate, maximum urethral closing pressure (MUCP), stress incontinence index score, and urgency incontinence index score were compared.

Methods, definitions, and units in this study conform to the standards recommended by the International Urogynecological Association and International Continence Society joint report on the terminology for female pelvic floor dysfunction [13].

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS-PC), version 15. Both categorical and continuous variables are reported as percentage, median, and range. Differences in dichotomous variables were tested using McNemar's test for paired variables and Pearson's Chi-Squared test for unpaired variables. Differences in continuous variables were tested using the Mann–Whitney U test. A significance level of 5 % was used.

Results

Recruitment and drop out of study participants is shown in Fig. 1. The 603 operations were performed by 21 surgeons. Median duration of follow-up was 129 months (range 114–160). Baseline characteristics are provided in Table 1 and primary outcome measures in Table 2.

Objective cure after 10 years was 89.9 %, and 2.3 % of the women had undergone repeat SUI surgery. Of the 11 patients (2.3 %) who had repeat SUI surgery, 9 received another TVT and 2 a bulking agent.

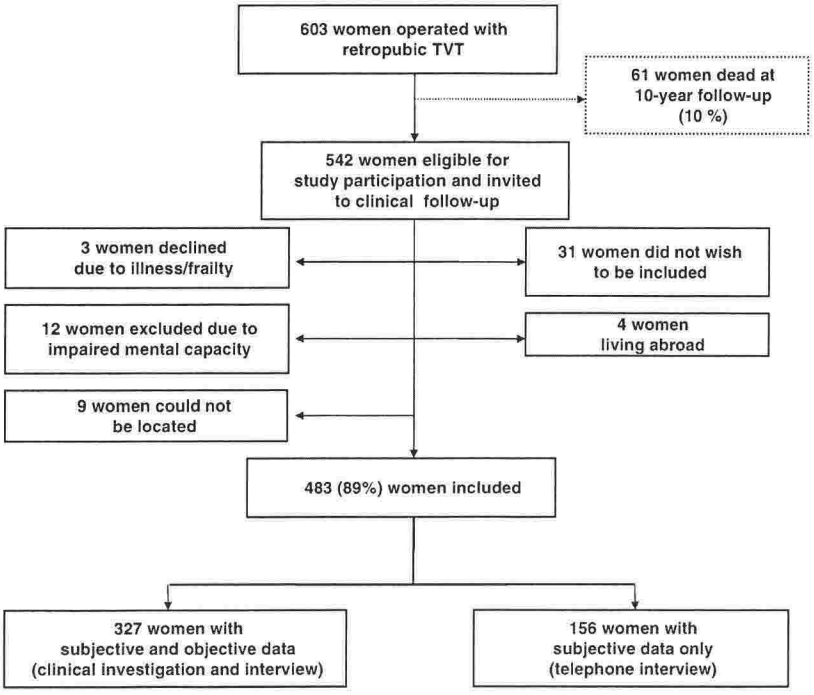

Fig. 1 Recruitment and drop-out of the study participants

Table 1 Baseline characteristics of the study participants at the 10-year follow-up (N=483)

Characteristics	
Demographics, median (range)	
Age (years)	64 (36–97)
BMI	26 (17–51)
Median time of follow-up (months)	129 (114–160)
Clinical characteristics, percentage (numbers/total/missing info)	
Topical estrogen use	16.7 (80/480/3)
Current smoking	21.7 (98/452/31)
Hysterectomy in the follow-up period	4.4 (21/482/1)
Pelvic organ prolapse surgery in the follow-up period	4.2 (20/481/2)
Current use of antimuscarinic medication	7.9 (38/481/2)

Primary subjective outcomes at the10-year follow-up were: 76.1 % cured, 18.0 % better, 3.4 % unchanged, and 2.5 % worse. The majority, 82.6 %, stated they were "very satisfied" with the operation.

Secondary outcomes are shown in Tables 3 and 4. Table 3 shows complications recorded during or immediately following surgery for a total complication rate of 8.7 %, the most common being hematomas of more than 4 cm in diameter.

Unfavorable long-term outcomes are shown in Table 4. Significantly more women had a low maximum flow rate and post-void residual above 100 ml at the 10-year follow-up compared with the preoperative data (Table 4). None had post-void residuals above 200 ml. There was an increase in de novo urgency incontinence from 6 to 12 months to 10 years post-surgery (4.1 % vs 14.9 %, p=0.01).

Subjective voiding difficulties were reported by 22.8 %, the most common being a slow stream or intermittency (Table 4). The percentage of women stating they were "very satisfied" with the treatment was similar for the women reporting voiding difficulties and those reporting no such problems (83.2 % vs 82.3 %, p=0.84). Furthermore, there was no difference in objectively low urinary flow (Q_{max}<15 ml/s) at the 10-year follow-up between the groups (27.7 % vs 27.1 %, p=0.92).

Only 1 case of asymptomatic mesh exposure was found at the 10-year follow-up. In addition, 3 mesh exposures had previously been recognized and surgically handled, bringing the total number of exposures to 4 (0.8 %) for the whole 10-year period. The surgical method used was excision of the exposed part of the tape and then re-suturing of the vaginal wall after mobilizing the edges of the defect.

This study revealed a small but significant decline in the percentage of women stating that they were "very satisfied" with the treatment from 6 to 12 months to 10 years post-surgery (89.1 % vs 82.6 %, p=0.006) despite no change in objective cure rates (90.2 % vs 89.9 %, Table 2).

Women stating that they were "very satisfied" had a significantly lower median urgency incontinence index score after 10 years compared with those not stating "very satisfied" (0 vs 5, p<0.001). Similar results were found when comparing women stating that they were "cured" after

Table 2 Primary objective and subjective outcome measures

Results	6–12 months Percentages (numbers/total/missing info)	10 years Percentages (numbers/total/missing info)	p value*
Objective results[a]	(N=327)	(N=327)	
Objective cure rate	90.2 (285/316/11)	89.9 (285/317/10)	0.86
Objective failure rate	9.8 (31/316/11)	10.1 (32/317/10)	0.86
	(N=483)	(N=483)	
Re-operation rate	0.6 (3/476/7)	2.3 (11/476/7)	0.008
Subjective results[b]	(N=480)	(N=472)	
Subjective cure rate	_[f]	76.1 (359/472/0)	
Subjective improved rate[c]	_[f]	94.1 (444/472/0)	
Subjective failure rate[d]	_[f]	5.9 (28/472/0)	
Treatment satisfaction rate[e]	89.1 (407/457/23)	82.6 (389/471/1)	0.006

*McNemar's test for paired variables

[a] Patients with repeat SUI surgery are classified as failures

[b] Patients with repeat SUI surgery are excluded

[c] Subjective improved rate defined as "cured" or "better"

[d] Subjective failure rate defined as "unchanged" or "worse"

[e] Percentage of women stating they were "very satisfied" with the treatment

[f] Subjective evaluation of the result was not part of the 6- to 12-month questionnaire and hence subjective cure rate, improved rate, and failure rate could not be calculated

Table 3 Secondary outcome measures I: complications registered during or immediately following surgery

Type of complications	Percentage (numbers/total/missing info)
Total	8.7 (42/483/0)
Hematoma (> 4 cm)	2.5 (12/483/0)
Superficial infection[a]	0.6 (3/483/0)
Deep infection[b]	0.8 (4/483/0)
Bladder perforations	1.2 (6/483/0)
Urethral injury	0.2 (1/483/0)
Bowel injury	0.0 (0/483/0)
Major vessel injury	0.0 (0/483/0)
Major bleeding (> 500 ml)	0.4 (2/483/0)
Catheterization>1 week	1.7 (8/483/0)
Catheterization>1 month	1.0 (5/483/0)
Postoperative vaginal mesh exposure	0.6 (3/479/4)
Postoperative sling release	1.9 (9/477/6)

[a] Local tenderness with redness and/or purulent discharge

[b] Abscess formation with or without sinus tract formation

10 years compared with those stating not "cured" (0 vs 4.5, $p<0.001$).

Patient characteristics of participating women operated on in the study departments differed from other TVT-operated women in the Registry Database only for the following preoperative variables: lower median post-void residuals (0 ml vs 5 ml, $p<0.001$), lower median MUCP (40 cm H_2O vs 45 cm H_2O, $p=0.03$), and higher median urgency incontinence index score (4 vs 3, $p<0.001$). There were no differences in median age, 24-hpad tests, stress tests, maximum flow rates or stress incontinence index scores.

Discussion

Our long-term follow-up study demonstrates an objective cure rate of 89.9 % after 10 years. This excellent result is in accordance with previous long-term follow-up studies of more selective and smaller study populations, reporting objective cure rates from 84 % to 93.1 % [4–8]. The subjective cure rate (76.1 %) in our study is also well within the 65–89.7 % range found by others [4–8]. The difference in objective and subjective cure rates found in our study (89.9 % vs 76.1 %) may be explained by de novo urgency incontinence symptoms. This assumption is based on our study demonstrating a significantly higher median 10-year urgency incontinence index score in the women stating that they were not cured compared with those stating that they were cured (score 4.5 vs 0, $p<0.001$). A similar difference was seen among women stating that they were "very satisfied" with their treatment compared with the others (score 0 vs 5, $p<0.001$).

We found the objective cure rate unchanged from 6 months to 10 years post-surgery ($p=0.86$, Table 2), in line with the publication by Serati et al. [5]. However, in contrast to Serati et al., who also showed stable subjective outcomes over a 10-year period, we found a small but significant decline in women stating that they were "very satisfied" from 6 months to 10 years post-surgery ($p=0.006$, Table 2) [5]. Given the heterogeneous nature of our patient population we still think it satisfactory that as many as 82.6 % state that they are "very satisfied" with the surgery given 10 years earlier; this is also higher than the 74 % demonstrated by Olsson et al. [6]. The subjective cure rate and treatment satisfaction rate found in our non-selected patient cohort 10 years after surgery are also encouraging compared with the 44 % cure rate14 years after Burch colposuspension [9].

The present study revealed a 4.2 % incidence of subsequent pelvic organ prolapse (POP) surgery after TVT (Table 1). The occurrence and development of POP have in the past been associated with Burch colposuspension [9, 14], but to a lesser degree with TVT [15]. Our finding of 4.2 % of patients having undergone subsequent POP surgery during follow-up after TVT may therefore add some insight into this potential association, but must not be mistaken for the true post-TVT incidence of POP, since our study was not designed to systematically evaluate persistent or de novo pelvic organ prolapse beyond recording any subsequent POP surgery.

Our study illustrates the difficulties encountered when evaluating long-term results in an ageing population. Recurrence of stress incontinence as well as recurrence or occurrence of POP, urgency, and urgency incontinence over time could be interpreted both as consequences of the surgical procedure 10 years previously as well as the effects of normal deterioration of the pelvic floor function caused by advancing age. The prevalence of urgency incontinence symptoms [16–19] and pelvic organ prolapse [20] are both known to increase with age . We have no comparable group of non-operated women followed over the same time period in order to control for age-associated incontinence symptoms.

It is well known that TVT may lead to bladder outlet obstruction [21]. We found a high number of women reporting voiding difficulties after 10 years, the majority complaining of a slow or intermittent urine stream (Table 4). However, the "very satisfied" rates were almost identical among those with and without subjective voiding problems (83.2 % vs 82.3 %, $p=0.84$) and there was no differences in objectively low urinary flow ($Q_{max}<15$ ml/s) between the groups (27.7 % vs 27.1 %, $p=0.92$). We therefore consider it unlikely that the reported voiding difficulty represents a serious clinical problem for these women at the present time.

Table 4 Secondary outcome measures II: unfavorable long-term outcomes[a]

	Percentage (numbers/total/missing info)		p value [c]
Objective voiding difficulties (among n=321)			
	Preoperative	10 years	
Q_{max}<15 ml/s	11.0 (18/164/157)	26.7 (79/296/25)	<0.001
Post-void residuals>100 ml	0.3 (1/310/11)	3.5 (11/313/8)	0.006
Post-void residuals>200 ml	0.0 (0/310/11)	0.0 (0/313/8)	
	At 6–12 months	10 years	
Q_{max}<15 ml/s	Incomplete data	26.7 (79/296/25)	
Post void residuals>100 ml	0.7 (2/306/15)	3.5 (11/313/8)	0.039
Asymptomatic vaginal mesh exposure (among n=321)		0.3 (1/317/4)	
Subjective voiding difficulties (among n=472)		22.8 (107/469/3)	
The 107 patients who reported voiding difficulties were categorized into the following groups			
A: Slow stream or intermittency		43.1 (44/102/5)	
B: Position-dependent micturition		5.9 (6/102/5)	
C: Need to immediately re-void		11.8 (12/102/5)	
D: Feeling of incomplete bladder emptying		7.8 (8/102/5)	
E: Straining to void		9.8 (10/102/5)	
F: Hesitancy		4.9 (5/102/5)	
G: More than one of the above		7.8 (8/102/5)	
H: Other		8.8 (9/102/5)	
Recurrent urinary tract infections (among n=472)		2.3 (11/471/1)	
Persistent painful voiding (among n=472)		1.1 (5/469/3)	
De novo urgency incontinence (among n=101)[b]			
	6–12 months	10 years	
	4.1 (4/98/3)	14.9 (15/101/0)	0.013

[a] For the evaluation of true 10-year secondary outcome measures the 11 re-operated patients were excluded (6 with objective data and 11 with subjective data)

[b] De novo urgency incontinence defined as postoperative urgency incontinence index >0 and having to use pads (among n=101 with preoperative urgency incontinence index =0)

[c] McNemar's test for paired variables

The low number of patients with post-void residuals above 100 at the 6- to 12-month evaluation also indicates that the voiding difficulties found at 10 years are more likely due to ageing than procedure-related. However, since no voiding cystometry was performed, we cannot exclude partial obstruction developing over time with compensatory increased detrusor pressure coexisting with normal flow and absence of post-void residuals in these patients. Further ageing could then theoretically cause these patients to experience increasing voiding difficulties in the future. Very few patients had objectively impaired voiding as assessed by high post-void residuals and/or low maximum flow rates (Table 4). In our study, 3.5 % of the women had post-void residuals above 100 ml at the 10-year clinical follow-up, which is a significant increase from the 0.3 % of women with a residual above 100 ml recorded before surgery and from the 0.7 % recorded at the 6- to 12-month follow-up (Table 4). However, only one of the women with high post-void residuals reported recurrent urinary tract infections. Also, an overestimation of post-void residuals may have occurred, since the women were examined only once and repeat measurement has been shown to produce lower volumes [22].

The large number of women included strengthens the results in this follow-up study. The use of a national registry removes the risk of selection bias that may occur when patient cohorts with specific inclusion and exclusion criteria are recruited to observational or randomized, controlled trials. Also, our national database better evaluates surgical outcomes in the routine clinical setting, as multiple surgeons with different levels of training perform the TVT procedures.

Another advantage of our study is that only high-volume TVT surgery departments participated, as variations in operating volumes have been shown to influence patient outcome [23].

The significantly lower median preoperative MUCP (40 vs 45 cm, p=0.03) and higher median preoperative urgency incontinence index score (4 vs 3, p<0.001) in our study compared with the other women in the national registry database further strengthens our results, as both a low

MUCP and mixed incontinence are associated with poorer outcomes [24, 25].

Our study has some limitations, including loss to follow-up (11 %), as lost patients can be interpreted as failures and therefore influence cure rates [26]. In our study few women were lost to follow-up. Being offered an opportunity for clinical evaluation would presumably be a strong motivation for women with failed surgery or dissatisfaction to join the study. We therefore think it unlikely that the women refusing participation were more dissatisfied with the TVT procedure than those agreeing to participate.

For this 10-year study, three supplemental, non-validated questions were added to the standard national follow-up questionnaire [11]. The questionnaire also lacked a question exploring de novo urgency without incontinence. However, 14.9 % of women reported de novo urgency incontinence in our study, and this is in accordance with de novo urgency incontinence rates of 1–17 % found after TVT in other publications [7, 27, 28].

Another weakness of our study could be that use of registry data includes the possibility of inaccuracies in the individual entries and the results must therefore always be interpreted with this in mind.

In conclusion, our study demonstrates excellent objective and subjective outcomes and a low number of re-operations in a non-selected cohort of women 10 years after retropubic TVT. The fact that these outcomes are found even when numerous surgeons have performed the operations, illustrates the robust properties of the procedure. The small but significant decline in treatment satisfaction 10 years after surgery, despite no difference in objective cure rates may be explained by an increase in urgency incontinence symptoms caused by advancing age.

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